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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,665	01/31/2002	Christine Leib-Mosch	10737-006001	2339

7590 11/26/2004

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/914,665	LEIB-MOSCH ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *12 November 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112 second paragraph rejection.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: *None*.

Claim(s) rejected: *1-6,8-12,20 and 21*.

Claim(s) withdrawn from consideration: *13-19*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

S Chen

SHIN-LIN CHEN
PRIMARY EXAMINER

Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the specification discloses i vitro use of the viral vector to express a recombinant protein in particular cell lines. Applicants cite "Training Materials" and argue that only one enabled use ocvering the scope of the claim is needed to enable the claim (amendment, p. 6-7). This is not found persuasive because of the reasons of record. The use of the viral vector in cell lines is to analyze the relative promoter activities of HERV-E, HERV-H, HERV-K-T47D, HERV-L and HERV-T in different cell lines in vitro. The specification fails to specifically states the use of the claimed viral vector for making recombinant protein. The eventual purpose of the claimed retroviral vector is for gene therapy in vivo as evidenced by the statement in the specification. The specification states "The present invention relates to retroviral expression vectors bearing promoters which may be cell-specifically controlled. The vectors are useful for example for the cell-specific expression of genes of therapeutic value in the context of a gene therapy" (specification, page 1). The claimed retroviral expression vector must have a use and the use of said retroviral expression vector is for gene therapy in vivo in light of the specification. Therefore, the claims read on using the claimed retroviral expression vectors or retroviral vector system for gene therapy in vivo in light of the specification. Further, the claims encompass using various promoter regions of different HERVs in a retroviral vector for cell-specific expression of desired genes. Sjottem et al., 1996 (Journal of Virology, Vol. 70, No. 1, p. 188-198) discloses that there are about 1,000 full-length elements and a similar numbe of solitary LTRs in HERV-H family of endogenous retrovirus-like elements and only a subset of HERV-H LTRs display promoter activity in human cell lines. The specification fails to provide adequate guidacne and evidnece for how to use various HERV LTRs in a retroviral expression vector for cell-specific expression in various cell types and sufficient expression of a desired gene product can be obtained so as to provide therapeutic effect for a particular disease or disorder for gene therapy in vivo via various administration routes .